



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ursula WIEDERMANN *et al.*

Application No: 10/562,064

Filed: June 17, 2004

For: Passive Immunotherapy Against
Malignant Melanoma

)
)
) Group Art Unit: Not Yet Assigned

)
) Examiner: Not Yet Assigned

MAIL STOP PCT

United States Patent and Trademark Office
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Renewed Petition Under 37 C.F.R. §1.47(a)

Sir:

This Renewed Petition Under 37 C.F.R. §1.47(a) and petition for a two-month extension of time to respond are being timely filed before the expiration of the extended statutory time period for reply, which falls on Saturday, March 15, 2007. For the reasons stated herein, the undersigned hereby respectfully requests reconsideration for status under 37 C.F.R. § 1.47(a), and for filing under 35 U.S.C. § 116.

I. SUMMARY

The above-identified national-stage application was filed with the United States Patent and Trademark Office on December 22, 2005 without a signed declaration. A Notice of Missing Requirements was mailed on January 25, 2007, requiring the oath or declaration. A Response to Notice of Missing Requirements and Petition Under 37 C.F.R. §1.47(a) was filed on August 27, 2007 ("Petition"). Exhibit 1.

On November 27, 2007, the Office of PCT Legal Administration issued a Decision on Petition Under 37 C.F.R. 1.47(a) ("Decision"), which indicated that Applicants' Petition was denied without prejudice. Exhibit 2 at 3. Under 37 C.F.R. 1.47(a), a grantable petition "must be accompanied by: (1) the fee under 37 CFR 1.17; (2) a statement of last known address of the non-signing inventor; (3) an oath or declaration executed by the other inventors on behalf of themselves and the non-signing inventor; and (4) factual proof that the inventor refuses to execute the application or cannot be reached after diligent effort." *Id.* at 2.

The Decision found that Applicants satisfied Items (1)-(3), but that Item (4) had not been satisfied. Specifically, "[u]ntil adequate supplemental materials are provided to confirm that a request for signature, accompanied by a copy of the complete application, has been sent to the non-signing inventor's last known address and that the inventor has refused to provide the requested signature in response to such request," Item (4) would not be satisfied. *Id.* at 3.

II. SUPPLEMENTAL PROOF THAT THE NON-SIGNING INVENTOR REFUSES TO EXECUTE THE APPLICATION PAPERS

On December 22, 2005, U.S. National-Stage Patent Application Serial No. 10/562,064 ("the '064 application") was filed under 35 U.S.C. § 371 in the names of Ursula Wiederman, Hubert Pehamberger, Otto Scheiner, Erika Jensen-Jarolim, Christoph Zielinski, Heimo Breiteneder, and Soldano Ferrone ("the named inventors"). The '064 application is a national-stage application of PCT International Application No. PCT/EP04/06519 ("the '06519 PCT application") and was filed without an executed oath or declaration. On January 25, 2007, the U.S. Patent and Trademark Office mailed a Notice of Missing Requirements, requiring an executed declaration as well as an additional claim fee.

Shortly thereafter, declaration and assignment documents were forwarded to attorneys in Europe (Kador & Partner) who in turn forwarded the documents to their client, Biolife Sciences

Forschungs- und Entwicklungsgesellschaft m.b.H. ("Biolife Sciences"), a Vienna-based biotechnology company and the named applicant for the '06519 PCT application. Biolife Sciences is a company located in Vienna, Austria, and was found by a group of scientists from the University of Vienna, including Dr. Hubert Pehamberger, Dr. Otto Scheiner, and Dr. Christoph Zielinski – all of whom are named inventors of this application. Exhibit 3 (Affidavit of Robert Schaechter). Robert Schaechter is the managing director of Biolife Sciences. *Id.*

On February 21, 2007, Prof. Pehamberger sent a copy of the Declaration associated with this application to Dr. Ferrone. Exhibit 4 (February 21, 2007 letter¹). Dr. Ferrone replied to Prof. Pehamberger on February 27, 2007, and stated he had difficulties in signing the Declaration and requested a copy of this patent application. Exhibit 5 (February 27, 2007 letter). Mr. Schaechter then sent a complete copy of this application to Dr. Ferrone by e-mail in February 2007. Exhibit 3.

As summarized in Applicants' previous petition, all of the named inventors other than Dr. Ferrone executed the declaration and assignment documents. After attempts to have Dr. Ferrone sign the declaration naming him as an inventor of the '064 application were unsuccessful in February 2007, Biolife Science's European attorneys advised the undersigned that Dr. Ferrone was inadvertently listed as an inventor of this application. Accordingly, a statement indicating that Dr. Ferrone's inclusion as an inventor of this application was inadvertent and without deceptive intent on his part was prepared and forwarded to Dr. Ferrone via Biolife Science in July 2007. Dr. Ferrone continued to refuse to sign any documents.

Mr. Schaechter sent a follow-up email to Dr. Ferrone on July 27, 2007 regarding his refusal to execute documents related to this application. *See* Exhibit 3, Annex 1. (e-mail string between Mr. Schaechter and Dr. Ferrone). Dr. Ferrone replied, "My understanding of the

¹ The letter was advertently dated February 21, 2006.

situation is that all the profits will go to the biotech company [Biolife Sciences] which has been set up in Vienna. Under these conditions I do not see any advantages for me to be part of the patent application." *Id.*

III. CONCLUSION

In view of the facts outlined above, the enclosed evidence, and the previously submitted Petition Under 37 C.F.R. 1.43(a), the undersigned respectfully submits that this application is entitled to status under 37 C.F.R. § 1.47(a). According to the Decision, no additional petition fee is required, however, the fee for a two-month extension of time (\$230) is included herewith.

If the Commissioner has any questions, the undersigned would appreciate a telephone call to the number indicated.

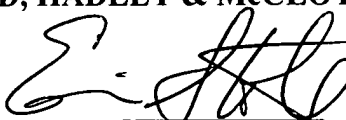
EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

MILBANK, TWEED, HADLEY & McCLOY LLP

March 17, 2008

By:


Einar Stole
Registration No. 47,272

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Tel. No. (202) 835-7553
Fax No. (202) 835-7586



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
 Ursula WIEDERMANN *et al.*)
)
 Application No: 10/562,064) Group Art Unit: Not Yet Assigned
)
 Filed: June 17, 2004) Examiner: Not Yet Assigned
)
 For: Passive Immunotherapy Against)
 Malignant Melanoma)

MAIL STOP PCT

United States Patent and Trademark Office
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response to Notice of Missing Requirements and Petition Under 37 C.F.R. §1.47(a)

Sir:

The above-identified national-stage application was filed with the United States Patent and Trademark Office on December 22, 2005 without a signed declaration. A Notice of Missing Requirements was mailed on January 25, 2007, requiring the oath or declaration. This response, petition, and petition for extension of time to respond are being timely filed before the expiration of the extended statutory time period for reply, which falls on Saturday, August 25, 2007. For the reasons stated herein, the undersigned hereby respectfully petitions for status under 37 C.F.R. § 1.47(a), and for filing under 35 U.S.C. § 116.

I. REQUIRED OATH OR DECLARATION

In accordance with 37 C.F.R. 1.497(b) and 1.47(a), Applicants submit herewith an executed declaration by all of the available joint inventors with the signature block of the single non-signing inventor, Dr. Soldano Ferrone, left blank.

II. PROOF THAT THE NON-SIGNING INVENTOR REFUSES TO EXECUTE THE APPLICATION PAPERS

On December 22, 2005, U.S. National-Stage Patent Application Serial No. 10/562,064 (“the ‘064 application”) was filed under 35 U.S.C. § 371 in the names of Ursula Wiederman, Hubert Pehamberger, Otto Scheiner, Erika Jensen-Jarolim, Christoph Zielinski, Heimo Breiteneder, and Soldano Ferrone (“the named inventors”). The ‘064 application is a national-stage application of PCT International Application No. PCT/EP04/06519 (“the ‘06519 PCT application”) and was filed without an executed oath or declaration. On January 25, 2007, the U.S. Patent and Trademark Office mailed a Notice of Missing Requirements, requiring an executed declaration as well as an additional claim fee. A copy of that notice is enclosed.

Shortly thereafter, declaration and assignment documents were forwarded to attorneys in Europe (Kador & Partner) who in turn forwarded the documents to their client, Biolife Sciences Forschungs- und Entwicklungsgesellschaft m.b.H. (“Biolife Sciences”), a Vienna-based biotechnology company and the named applicant for the ‘06519 PCT application. Robert Schaechter, the manager director for Biolife Sciences, sent a Declaration for Dr. Ferrone to execute immediately after receiving the documents from Kador and Partner in February 2007. *See Exhibit 1 (declaration from Mr. Schaechter).*

All of the named inventors other than Dr. Ferrone executed the declaration and assignment documents, and copies of the executed declaration and assignment documents are enclosed. After attempts to have Dr. Ferrone sign the declaration naming him as an inventor of the ‘064 application were unsuccessful, Biolife Science’s European attorneys advised the undersigned that Dr. Ferrone was inadvertently listed as an inventor of this application. Accordingly, a statement indicating that Dr. Ferrone’s inclusion as an inventor of this application

was inadvertent and without deceptive intent on his part was prepared and forwarded to Dr.

Ferrone via Biolife Science in July 2007. Dr. Ferrone continued to refuse to sign any documents.

Mr. Schaechter sent a follow-up email to Dr. Ferrone on July 27, 2007 regarding his refusal to execute documents related to this application. *See* Exhibit 2 (e-mail string between Mr. Schaechter and Dr. Ferrone with personal information redacted). Dr. Ferrone replied, "My understanding of the situation is that all the profits will go to the biotech company [Biolife Sciences] which has been set up in Vienna. Under these conditions I do not see any advantages for me to be part of the patent application." *Id.*

Because of Dr. Ferrone's refusals, further review and investigation was conducted. Based on the information gathered so far, the undersigned concludes that Dr. Ferrone should still be listed as an inventor at this time. The undersigned has made preparations to interview the named inventors, including Dr. Ferrone, and will make a final determination of inventorship of this application as soon as all necessary factual information can be obtained.

III. LAST KNOWN ADDRESS OF THE NON-SIGNING INVENTOR

The last known address of Dr. Ferrone is Department of Immunology, Roswell Park Cancer Institute, Elm & Carlton Streets, Buffalo, New York, 14263.

IV. CONCLUSION

In view of the facts outlined above, the enclosed evidence, and the executed Oath/Declaration from Ms. Wiedermann, Mr. Pehamberger, Mr. Otto, Ms. Jensen-Jarolim, Mr. Zielinski, and Mr. Breiteneder, the undersigned respectfully submits that this application is entitled to status under 37 C.F.R. § 1.47(a).

The required petition fee under 1.17(g) (\$200), fee for missing requirement surcharge (\$65), fee for multiple dependent claim surcharge (\$180), and fee for extension of time 5 months (\$1,080) are included herewith (total \$1,525).

If the Commissioner has any questions, the undersigned would appreciate a telephone call to the number indicated.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

MILBANK, TWEED, HADLEY & McCLOY LLP

August 27, 2007

By: *Enrique Longton* ^{Enrique Longton}
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Registration No. 47,272

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15 NOV 2007

UNITED STATES PATENT AND TRADEMARK OFFICE



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United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

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INTERNATIONAL SQUARE BUILDING
1850 K STREET, SUITE 1100
WASHINGTON, DC 20006

In re Application of:
WIEDERMANN, Ursula, et al.
U.S. Application No.: 10/562,064
PCT No.: PCT/EP2004/006519
International Filing Date: 17 June 2004
Priority Date: 23 June 2003
Atty's Docket No.: 37488.00900US
For: PASSIVE IMMUNE THERAPY
AGAINST MALIGNANT
MELANOMA

DECISION ON PETITION UNDER
37 CFR 1.47(a)

This decision is issued in response to applicants' "Response to Notice of Missing Requirements and Petition Under 37 CFR 1.47(a)" filed 27 August 2007. Applicants have paid the required petition fee.

BACKGROUND

On 17 June 2004, applicants filed international application PCT/EP2004/006519. The international application claimed a priority date of 23 June 2003, and it designated the United States. On 06 January 2005, the International Bureau (IB) communicated a copy of the international application to the United States Patent and Trademark Office (USPTO). The deadline for submission of the basic national fee was thirty months from the priority date, i.e., 23 December 2005.

On 22 December 2005, applicants' filed a Transmittal Letter for entry into the national stage in the United States accompanied by, among other materials, payment of the basic national fee and a translation of the international application into English.

On 25 January 2007, the United States Designated/Elected Office (DO/EO/US) mailed a Notification Of Missing Requirement (Form PCT/DO/EO/905) indicating that an executed declaration in compliance with 37 CFR 1.497, the surcharge for filing the oath or declaration later than thirty months after the priority date, and \$180 in additional claims fees were required.

On 27 August 2007, applicants filed a response to the Notification Of Missing Requirements (with required five-month extension fee). The response included payment of the

required surcharge and claims fees, a partially executed declaration, and the petition under 37 CFR 1.47(a) considered herein. The petition seeks acceptance of the application without the signature of inventor Soldano FERRONE, whom applicants assert has refused to execute the application.

DISCUSSION

A grantable petition under 37 CFR 1.47(a) must be accompanied by: (1) the fee under 37 CFR 1.17; (2) a statement of the last known address of the non-signing inventor; (3) an oath or declaration executed by the other inventors on behalf of themselves and the non-signing inventor; and (4) factual proof that the inventor refuses to execute the application or cannot be reached after diligent effort.

Applicants here have provided the required petition fee, and the petition states the last known address of the non-signing inventor. Items (1) and (2) are therefore satisfied.

Regarding item (3), section 409.03(a) of the Manual of Patent Examining Practice (MPEP) states that:

An oath or declaration signed by all the available joint inventors with the signature block of the nonsigning inventor(s) left blank may be treated as having been signed by all the joint inventors on behalf of the nonsigning inventor(s), unless otherwise indicated.

Here, applicants have filed a declaration executed by the inventors of record in the international application and including an unsigned signature block for the non-signing inventor, Soldano FERRONE. This declaration can be accepted as having been executed by the signing inventors on their own behalf and on behalf of the non-signing inventor. Item (3) is therefore satisfied.

Regarding item (4), MPEP section 409.03(d) states that, before it can be concluded that an inventor has refused to execute the application papers, "[a] copy of the application papers should be sent to the last known address of the nonsigning inventor, or, if the nonsigning inventor is represented by counsel, to the address of the nonsigning inventor's attorney." The MPEP also states the following:

Where a refusal of the inventor to sign the application papers is alleged, the circumstances of the presentation of the application papers and of the refusal must be specified in a statement of facts by the person who presented the inventor with the application papers and/or to whom the refusal was made. Statements by a party not present when an oral refusal is made will not be accepted.

Here, as evidence of the inventor's refusal to execute the declaration, applicants have provided a letter from Robert Schaechter stating that he sent a copy of the declaration to the non-signing inventor, as well as a copy of email communications between Mr. Schaechter and the non-signing inventor. However, as discussed in the MPEP, before it can be concluded that the

inventor has refused to execute the application, applicants are required to provide evidence that a copy of the complete application (specification, claims, and drawings) and a request for signature has been forwarded to the last known address of the inventor. The materials provided here refer only to the declaration being sent to the inventor. In addition, applicants must provide any available documentary evidence to confirm such mailing (i.e., a copy of the cover letter used, a confirmation receipt confirming delivery, etc). In addition, a firsthand statement clarifying the contents of the email correspondence must be provided (it is noted that the emails refer to a refusal to cooperate purportedly made by the inventor in correspondence to a person named "Hubert," but no firsthand information has been provided regarding such refusal).

Until adequate supplemental materials are provided to confirm that a request for signature, accompanied by a copy of the complete application, has been sent to the non-signing inventor's last known address and that the inventor has refused to provide the requested signature in response to such request, item (4) is not satisfied.

CONCLUSION

Applicants' petition under 37 CFR 1.47(a) is **DISMISSED** without prejudice.

If reconsideration on the merits of the petition is desired, a proper response must be filed within **TWO (2) MONTHS** of the mail date of the present decision. Any request for reconsideration should include a cover letter entitled "Renewed Petition Under 37 CFR 1.47(a)" and must include the additional materials required to satisfy item (4) of a grantable petition, as discussed above. No additional petition fee is required.

Failure to file a proper response will result in abandonment of the application. Extensions of time are available under 37 CFR 1.136(a)

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.



Richard M. Ross
Attorney Advisor
Office of PCT Legal Administration
Telephone: (571) 272-3296
Facsimile: (571) 273-0459



Affidavit

I, the undersigned, make this statement for the purpose of filing with the United States Patent and Trade Mark Office. The following statement is given according to my best knowledge and believe. I am fully aware that giving a false statement in lieu of an oath is a criminal offence.

I, Robert Schächter, am managing director of the company BioLife Science Forschungs- und Entwicklungsges.m.b.H (in the following referred to as "BioLife Science") since 2000. "BioLife" Science is a small entity company located in Vienna, Austria, and was founded in the year 2000 by a group of scientists from the University of Vienna - Prof. Dr. Hubert Pehamberger, Prof. Dr. Otto Scheiner and Prof. Dr. Christoph Zielinski - and Euro Capital Partners, a company specialized in seed financing and management of innovative enterprises.

As managing director of the company I am fully responsible for the company and therefore also for intellectual property rights, in particular I am accountable for all formal matters regarding intellectual property rights .

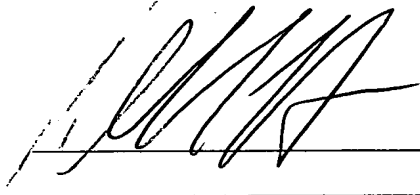
I submit this affidavit in support of our evidence showing that a copy of the complete US patent application 10/562,064 (specification, claims and drawings), and request for Prof. Dr. Ferrone's signature was sent by e-mail (printout thereof in Annex 1) to his last known address by BioLife Science.

The US Patent application 10/562,064 is based on the International Patent Application PCT/EP2004/006519 "Passive Immune Therapy against malignant melanoma" and claims an invention which was made during a scientific cooperation between Prof. Dr. Ferrone and BioLife Science.

All through the generation of said patent application Dr. Ferrone was involved by BioLife Science.

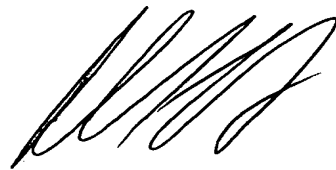
Furthermore, in February 2007 when I asked in the name of BioLife Science Prof. Dr. Ferrone for signing the inventor declaration, I send also a copy of the complete application as field with the USPTO to Prof. Dr. Ferrone by e-mail. As it has been already pointed out in our last submission, all attempts to convince Prof. Ferrone to sign the declaration were in vain.

I confirm that all statements made above are given to my best knowledge and believe.



Robert Schächter in Vienna, date

20080203



Robert Schächter

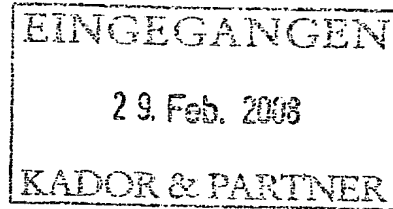
Robert Schaechter

Von:
Gesendet:
An:
Cc:

Betreff:



Ferrone, Soldano [Soldano.Ferrone@RoswellPark.org]
Freitag, 27. Juli 2007 17:47
Robert Schaechter
Christoph. Zielinski@Meduniwien. Ac. At; Hubert. Pehamberger@Meduniwien. Ac. At
RE: Biolifescience



Dear Mr. Schaechter,

Thank you for your e-mail with the enclosed information. My understanding of the situation is that all the profits will go to the biotech company which has been set up in Vienna. Under these conditions I do not see any advantages for me to be part of the patent application. Is my understanding correct?

If you need any additional information please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,
Soldano

Soldano Ferrone, M.D., Ph.D.
Department of Immunology
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, New York 14263 (USA)
Phone: (716) 845-8534
Fax: (716) 845-7613
E-mail: soldano.ferrone@roswellpark.org

-----Original Message-----

From: Robert Schaechter [mailto:schaechter@ecp.co.at]
Sent: Friday, July 27, 2007 6:19 AM
To: Ferrone, Soldano
Cc: Christoph. Zielinski@Meduniwien. Ac. At; Hubert. Pehamberger@Meduniwien. Ac. At
Subject: Biolifescience

> Dear Prof.Ferrone,
>
> firstly I hope you are doing well and you enjoy the summer as we do in
>
> Vienna.
>
> I wanted to come back to your discussions and correspondence with
> Hubert regarding the patent situation "Mimotope".
> We have been in agreement to pursue in common interest the cancer
> vaccination patenting process.
> We have signed a related co operation and consultancy agreement.
> As the patenting process is under development we have sent related
> documents for signature, asking for your agreement being one of the
> "Co-inventors" as we have seen that as a contribution to deepen our
> cooperative relation.
> I understood from your correspondence with hubert that you do not feel
> comfortable signing the document as co-inventor - even I have
> difficulties to understand your decision - because there is no
> obligation involved - it should just guarantee your rights in case of
> success - I consequently understand you want to be deleted from the
> list - therefore I am sending a declaration confirming you are only

> "accidentally" on the patent.
>
> We kindly ask you to sign one of the documents, because either you
> want to stay on our common board - or you want to leave. We respect
> both decisions, definitely would prefer having you with us - specially

> as we are hoping for positive results being eventually as well in your

> interest.
>
> Please let us know about your decision - if you need more information
> - or you have additional proposals - please do not hesitate contacting

> me.
>
> I hope to be meeting with you in near future and remain
>
> With my best regards
> Yours sincerely
>
> Robert Schaechter

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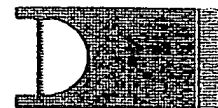
A handwritten signature in black ink, appearing to be 'R. Schaechter', with a long horizontal stroke extending to the right.

Ammed 1



MEDICAL
UNIVERSITY
OF VIENNA

DIVISION OF GENERAL DERMATOLOGY
DEPARTMENT OF DERMATOLOGY



Professor and Chairman: Hubert Pehamberger MD

Vienna, February 21, 2006

Soldano Ferrone, MD, PhD
Department of Immunology
Rosewell Park Cancer Institute
Ekn & Carlton Streets
Buffalo, NY 14263
USA

FAX: 001 716 845-7613

Dear Soldano:

Enclosed please find a description of the patent which has to be signed by all investigators. Please sign the FAX and return it by FAX and by mail. Thank you in advance.

In addition and most importantly, I hope you are fine and I hope we will meet in the near future. Please let me know when you will be in Europe. Perhaps we can arrange that you step by in Vienna. I think it would be important to have further discussion on our project.

Best regards,

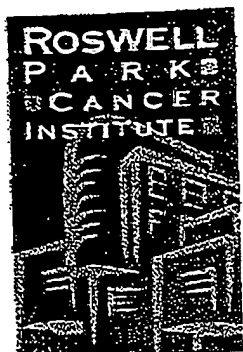
Hubert Pehamberger

encl.

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Amex 2

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Buffalo, New York 14263Soldano Ferrone, M.D., Ph.D.
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Fax

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TO: Dr. Hubert Pehamberger
FROM: Soldano Ferrone, M.D., Ph.D.
DATE: February 27, 2007

FAX NO: 43-1-40400-7699

TEL. NO: 716-845-8534

NO. OF PAGES: 3 (includes cover)

Dear Hubert,

Thank you for your fax dated February 21, 2007, containing the enclosed material. As you might know, I had received a similar request from Ursula. I hoped I would receive a copy of the patent application and of the agreement with the company.

I have difficulties in signing the document that Ursula and you sent to me since I am not aware of its content and I am concerned that there may be conflicts with other applications we have been working on.

Please arrange that a copy of the patent and of the agreement with the company is sent to me so that we can address this point in a timely fashion.

If you need any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

Soldano